REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Objection and amendment to the specification

At page 2 of the Office Action, the specification stands objected to for the alleged introduction of new matter. The objection states:

> the only teaching that can be reasonably incorporated from Unexamined Patent Application No. WO 92-19759 is an antibody comprising the complete disclosed V_H and V_L regions of hPM-l.

Applicants respectfully traverse. Solely to advance prosecution, however, and not in acquiescence to the objection, Applicants withdraw the prior attempt to amend the specification and now request amendment to the specification to incorporate complete V_H and V_L chains. A replacement sequence listing is also enclosed to provide the sequence of complete V_H and V_L chains. SEQ ID NOs 20 and 18 are the amino acid sequences of SEQ ID NOs 19 and 17 (presenting both amino acid and DNA sequences), which, in turn, correspond to SEQ ID NOs: 57 and 56 in WO 92/19759.

The scope of the amendments to the specification complies with that which the Office considers to be "reasonable." Accordingly, the objection is respectfully believed to be overcome.

Support for the amendment to the specification may also be found at pages 10-11, which recite:

> Reshaped human antibodies may also be used according to the invention. These are prepared by using the complementary determinant region of a mouse or other non-human mammalian animal antibody to replace the complementary determinant region of a human antibody, and conventional gene recombination methods therefor are well-known. One of the known methods may be used to obtain a reshaped human antibody which is useful according to the invention. A preferred example of such a reshaped human antibody is hPM-1 (see Intl.

> Unexamined Patent Application No. W092-19759).
>
> When necessary, amino acids of the framework (FR) region of the variable region of an antibody may be substituted so that the complementary determinant region of the reshaped human antibody forms a suitable antibody binding site (Sato et al., Cancer Res. 53:851-856, 1993).

Within WO 92/19759 may be found the sequences of the V_H and V_L, as V_H version **f** and V_L version **a**. These sequences are listed as SEQ ID NOs 56 and 57 in WO 92/19759, but have been changed to SEQ ID NOs 18 and 20 in this application, to comply with the sequence rules, as noted above.

The present sequences of the V_H and V_L are also supported by the incorporation by reference of Sato *et al.*, Cancer Res. 53:851-856 (1993) ("Sato"), provided with the January 9, 2001 IDS as document A45. Page 852, right column, of Sato describes that "the light chain version **a** plus the heavy chain version **f** clearly provided the best reshaped human PM-l antibody"; and that "Fig. 5 shows that the reshaped human PM-l antibody (a combination of the light chain version **a** and the heavy chain version **f**) is effective in inhibiting. Page 855, the left column, of Sato describes that "the reshaped human PM-I antibody inhibits multiple myeloma cell growth as well as the original mouse PM-I antibody does in vivo (fig.5)." Therefore, prior to the priority date of the present application, the combination of the L chain version **a** and the H chain version **f** described in WO92/19759 was known as a humanized PM-l antibody.

II. Status of the claims

Claims 1-8, 10-12 and 15-25 are cancelled, and claims 9 and 13 are amended. The amendment to claims 9 and 13 defines the V_H and V_L chains according to both the CDR and FR, and is supported by pages 10 and 11, as presently amended. The foregoing amendments are made solely to advance prosecution and not in acquiescence to any rejection, reserving the right to pursue cancelled subject matter in one or more continuing applications having the same right of priority as the present application.

After amending the claims as set forth above, claims 9, 13 and 14 are pending.

III. Rejection under 35 U.S.C. § 112, first paragraph

At pages 2-4 of the Office Action, the Office maintains the prior rejection of claims 9, 13 and 14 as allegedly failing to comply with the written description requirement. This rejection has two aspects.

The first aspect follows from the objection to the previous attempts to amend the specification – because the amendments were not entered, the claims allegedly lacked support in the specification. This aspect is traversed but is now believed to be overcome because the specification incorporates subject matter that the Office considers to be "reasonable," and the claims reflect that subject matter.

The second aspect of the rejection alleges that:

> the instant specification discloses no teaching of the use of a subgenus of antibodies for inhibiting synovial cell growth or the treatment of arthritis, said subgenus of antibodies being described only by the six V_H and V_L CDR regions of any antibody, including the hPM-1 antibody of Unexamined Patent Application No. WO 92-19759 which is actually the single hPM-1 antibody of Hirata et al. (1989).

Office Action at page 3. Applicants respectfully traverse. Nevertheless, this aspect of the rejection is also respectfully believed to be overcome since the claims do not recite a subgenus described only by the six V_H and V_L CDR regions of any antibody, as complete V_H and V_L are now defined.

Accordingly, the written description rejection is respectfully believed to be overcome. Reconsideration and withdrawal are respectfully requested.

IV. Obviousness type double patenting

At page 4 of the Office Action, claims 9, 13, and 14 are provisionally rejected as obvious variants of claims 1, 9, and 10 of U.S. Patent Application No. 11/585,172. Applicants respectfully traverse the rejection because the claims are not obvious variants of each other. Without acquiescing to the Examiner's rejection, Applicants respectfully request

that the provisional rejection be held in abeyance, pending the identification of otherwise allowable subject matter.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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